AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

CLAIMS

Claim 1 (original): An intraorally rapidly disintegrable tablet which comprises fine granules prepared by granulating a mixture of a water-soluble pharmacologically active ingredient and an adsorbent, D-mannitol and a disintegrator.

Claim 2 (original): The intraorally rapidly disintegrable tablet as claimed in Claim 1, wherein the adsorbent is at least one member selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate.

Claim 3 (currently amended): The intraorally rapidly disintegrable tablet as claimed in Claim 1 ~~or 2~~, wherein the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

Claim 4 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 1 to 3~~Claim 1, wherein the whole or a part of the D-mannitol is a primary particle and the specific surface area of the primary particle is 1.0 m^2/g or less.

Claim 5 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 1 to 4~~Claim 1, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

Claim 6 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 1 to 4~~Claim 1, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

Claim 7 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 1 to 6~~Claim 1, further containing a lubricant.

Claim 8 (original): The intraorally rapidly disintegrable tablet as claimed in Claim 7, wherein the lubricant is contained only on the surface of the tablet.

Claim 9 (currently amended): The intraorally rapidly disintegrable tablet as claimed in Claim 7~~ or 8~~, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

Claim 10 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 1 to 9~~Claim 1, further containing at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

Claim 11 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 1 to 10~~Claim 1, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent in the fine granules is 1:10 to 10:1.

Claim 12 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 1 to 11~~Claim 1, wherein the compounding ratio of the fine granules in the tablet is 1 to 50% by weight.

Claim 13 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 1 to 12~~Claim 1, wherein the compounding ratio of the D-mannitol in the tablet is 20 to 99% by weight.

Claim 14 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 1 to 13~~Claim 1, wherein the compounding ratio of the disintegrator in the tablet is 0.5 to 30% by weight.

Claim 15 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 1 to 14~~Claims 1, wherein the hardness of the tablet is 20N or higher.

Claim 16 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 1 to 15~~Claims 1, wherein the disintegration time in oral cavity is 30 seconds or less.

Claim 17 (original): A process for producing an intraorally rapidly disintegrable tablet which comprises mixing fine granules prepared by granulating a mixture of a water-soluble pharmacologically active ingredient and an adsorbent, D-mannitol and a disintegrator to prepare a material for compression molding, and subjecting the material to compression molding.

Claim 18 (original): The process as claimed in Claim 17, wherein the adsorbent is at least one member selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate.

Claim 19 (currently amended): The process as claimed in Claim 17 ~~or 18~~, wherein the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

Claim 20 (currently amended): The process as claimed in ~~any one of Claims 17 to 19~~Claim 17, wherein the whole or a part of the D-mannitol is a primary particle and the specific surface area of the primary particle is 1.0 m^2/g or less.

Claim 21 (currently amended): The process as claimed in ~~any one of Claims 17 to 20~~Claim 17, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

Claim 22 (currently amended): The process as claimed in ~~any one of Claims 17 to 20~~Claim 17, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

Claim 23 (currently amended): The process as claimed in ~~any one of Claims 17 to 22~~Claim 17, wherein the material for compression molding contains a lubricant.

Claim 24 (currently amended): The process as claimed in ~~any one of Claims 17 to 23~~Claim 17, wherein the compression molding is carried out using a compression molding machine in which a lubricant is previously applied on the surface of punch and the die.

Claim 25 (currently amended): The process as claimed in Claim 23 ~~or 24~~, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

Claim 26 (currently amended): The process as claimed in ~~any one of Claims 17 to 25~~Claim 17, wherein the material for compression molding contains at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

Claim 27 (currently amended): The process as claimed in ~~any one of Claims 17 to 26~~Claim 17, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent in the fine granules is 1:10 to 10:1.

Claim 28 (currently amended): The process as claimed in ~~any one of Claims 17 to 27~~Claim 17, wherein the compounding ratio of the fine granules in the tablet is 1 to 50% by weight.

Claim 29 (currently amended): The process as claimed in ~~any one of Claims 17 to 28~~Claim 17, wherein the compounding ratio of the D-mannitol in the tablet is 20 to 99% by weight.

Claim 30 (currently amended): The process as claimed in ~~any one of Claims 17 to 29~~Claim 17, wherein the compounding ratio of the disintegrator in the tablet is 0.5 to 30% by weight.

Claim 31 (original): An intraorally rapidly disintegrable tablet which is produced by mixing fine granules prepared by granulating a mixture of a water-soluble pharmacologically active ingredient and an adsorbent D-mannitol and a disintegrator to prepare a material for compression molding and subjecting the material to compression molding.

Claim 32 (original): The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the adsorbent is at least one member selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate.

Claim 33 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claim 31 or 32~~Claim 31, wherein the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

Claim 34 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 31 to 33~~Claim 31, wherein whole or a part of the D-mannitol is a primary particles and the specific surface area of the primary particle is 1.0 m^2/g or less.

Claim 35 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 31 to 34~~Claim 31, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

Claim 36 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 31 to 34~~Claim 31, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

Claim 37 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 31 to 36~~Claim 31, wherein the material for compression molding contains a lubricant.

Claim 38 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 31 to 37~~Claim 31, wherein the compression molding is carried out using a compression molding machine in which a lubricant is previously applied on the surface of punch and the die.

Claim 39 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~Claim 37 or 38~~Claim 37, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

Claim 40 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 31 to 39~~Claim 31, wherein the material for compression molding contains at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

Claim 41 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 31 to 40~~Claim 31, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent in the fine granules is 1:10 to 10:1.

Claim 42 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 31 to 41~~Claim 31, wherein the compounding ratio of the fine granules in the tablet is 1 to 50% by weight.

Claim 43 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 31 to 42~~Claim 31, wherein the compounding ratio of the D-mannitol in the tablet is 20 to 99% by weight.

Claim 44 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 31 to 43~~Claim 31, wherein the compounding ratio of the disintegrator in the tablet is 0.5 to 30% by weight.

Claim 45 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 31 to 44~~Claim 31, wherein the hardness of the tablet is 20N or higher.

Claim 46 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 31 to 45~~Claim 31, wherein the disintegration time in oral cavity is 30 seconds or less.

Claim 47 (original): A process for producing an intraorally rapidly disintegrable tablet which comprises granulating a mixture of a water-soluble pharmacologically active ingredient, an adsorbent, D-mannitol and a disintegrator to prepare a material for compression molding, and subjecting the material to compression molding.

Claim 48 (original): The process as claimed in Claim 47, wherein the adsorbent is at least one member selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate.

Claim 49 (currently amended): The process as claimed in Claim 47 ~~or 48~~, wherein the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

Claim 50 (currently amended): The process as claimed in ~~any one of Claims 47 to 49~~Claim 47, wherein whole or a part of the D-mannitol is a primary particle and the specific surface area of the primary particle is 1.0 m^2/g or less.

Claim 51 (currently amended): The process as claimed in ~~any one of Claims 47 to 50~~Claim 47, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

Claim 52 (currently amended): The process as claimed in ~~any one of Claims 47 to 50~~Claim 47, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

Claim 53 (currently amended): The process as claimed in ~~any one of Claims 47 to 52~~Claim 47, wherein the material for compression molding contains a lubricant.

Claim 54 (currently amended): The process as claimed in ~~any one of Claims 47 to 53~~Claim 47, wherein the compression molding is carried out using a compression molding machine in which a lubricant is previously applied on the surface of punch and the die.

Claim 55 (currently amended): The process as claimed in Claim 53 ~~or 54~~, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

Claim 56 (currently amended): The process as claimed in ~~any one of Claims 47 to 55~~Claim 47, wherein the compression molding material ~~containis~~contains at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

Claim 57 (currently amended): The process as claimed in ~~any one of Claims 47 to 56~~Claim 47, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent in the compression molding material is 1:10 to 10:1.

Claim 58 (currently amended): The process as claimed in ~~any one of Claims 47 to 57~~Claim 47, wherein the compounding ratio of the water-soluble pharmacologically active ingredient and the adsorbent in the tablet is 1 to 50% by weight.

Claim 59 (currently amended): The process as claimed in ~~any one of Claims 47 to 58~~Claim 47, wherein the compounding ratio of the D-mannitol in the tablet is 20 to 99% by weight.

Claim 60 (currently amended): The process as claimed in ~~any one of Claims 47 to 59~~Claim 47, wherein the compounding ratio of the disintegrator in the tablet is 0.5 to 30% by weight.

Claim 61 (original): An intraorally rapidly disintegrable tablet which comprises a water-soluble pharmacologically active ingredient, an adsorbent, D-mannitol and a disintegrator.

Claim 62 (original): The intraorally rapidly disintegrable tablet as claimed in Claim 61, wherein the adsorbent is at least one member selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate.

Claim 63 (currently amended): The intraorally rapidly disintegrable tablet as claimed in Claim 61 ~~or 62~~, wherein the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

Claim 64 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 61 to 63~~Claim 61, wherein whole or a part of the D-mannitol is a primary particle and the specific surface area of the primary particle is 1.0 m^2/g or less.

Claim 65 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 61 to 64~~Claim 61, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

Claim 66 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 61 to 64~~Claim 61, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

Claim 67 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 61 to 66~~Claim 61, containing a lubricant.

Claim 68 (original): The intraorally rapidly disintegrable tablet as claimed in Claim 67, wherein the lubricant is contained only on the surface of the tablet.

Claim 69 (currently amended): The intraorally rapidly disintegrable tablet as claimed in Claim 67 ~~or 68~~, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

Claim 70 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 61 to 69~~Claim 61, further containing at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

Claim 71 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 61 to 70~~Claim 61, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent is 1:10 to 10:1.

Claim 72 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 61 to 71~~Claim 61, wherein the compounding ratio of the water-soluble pharmacologically active ingredient and the adsorbent in the tablet is 1 to 50% by weight.

Claim 73 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 61 to 72~~Claim 61, wherein the compounding ratio of the D-mannitol in the tablet is 20 to 99% by weight.

Claim 74 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 61 to 73~~Claim 61, wherein the compounding ratio of the disintegrator in the tablet is 0.5 to 30% by weight.

Claim 75 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 61 to 74~~Claim 61, wherein the hardness of the tablet is 20N or higher.

Claim 76 (currently amended): The intraorally rapidly disintegrable tablet as claimed in ~~any one of Claims 61 to 75~~Claim 61, wherein the disintegration time in the oral cavity is 30 seconds or less.